

# News from Ed Markey

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CONTACT: Tara McGuinness or

Kate Reinhalter

(202) 225-2836

## **Rep. Markey Questions FDA Advisory Committee Decision to Ignore Potential Conflicts of Interest**

*FDA waives ethics rules for doctors associated with drug companies*

**Washington, D.C.** – Rep. Edward J. Markey (D-MA), a Senior Member of the Energy and Commerce Committee, sent a letter today to the Food and Drug Administration (FDA) questioning its decision to absolve members of the advisory committee reviewing the safety of cox-2 inhibitors (Vioxx, Bextra and Celebrex) from any potential conflicts of interest. The FDA determined that due to the general nature of the issues at hand the members of the committee were not subject to the standard rules regarding conflicts of interest and thus not obligated to disclose any potential conflicts.

However, an investigation by the Center for Science in the Public Interest and the New York Times revealed that 10 of the 32 members who sat on the Cox-2 inhibitors advisory panel had ties to the pharmaceutical industry. According to the New York Times, if the 10 members of the panel had recused themselves from voting, then Bextra would have been withdrawn (12 to 8) and Vioxx would not have been allowed to return to the market (14 to 8).

Rep. Markey said, “I am concerned that the integrity of the review process may have been compromised by not following standard procedures regarding conflicts of interest and that the outcome of this advisory committee meeting would have been different if only those who were independent of industry had voted. For the past several months many patients have been confused and worried about what pain medications are safe for them to take. This meeting was supposed to finally provide consumers and physicians with some real, unbiased guidance on the risks and benefits of these drugs. In order for the public to trust the recommendations of the advisory committee, they need to know that patient well-being is their only concern and they are not being influenced by any relationships with the pharmaceutical industry.”

The New York Times reported that before each of the FDA advisory committee meetings, a secretary from the FDA read a statement to absolve the potential conflicts of interest among committee members. The FDA secretary said that the agency "acknowledges that there may be potential conflicts of interest, but because of the general nature of the discussions before the committee, these potential conflicts are mitigated." If the FDA had determined that topic (the benefits and risks associated with Vioxx, Bextra, Celebrex and other cox-2 inhibitors) was specific in nature, the members of the committee would have been required to disclose their potential conflicts of interest and perhaps obtain waivers in order to participate in the meeting.

Rep. Markey said, “I am curious about FDA’s determination in this matter. I believe that the issues discussed were very specific and had enormous consequences for the two companies that make Vioxx and Bextra: Merck and Pfizer. Although the panel was not approving any drugs, they were trying to decide whether to revoke the approval of a drug. This could arguably have more impact on the reputation and financial well-being of a company than an approval. The fact that Merck and Pfizer’s stock increased significantly the day after the decision was made shows that these decisions had significant financial implications.”

Rep. Markey said, “It is critical that the people who are charged with making these important recommendations reveal any potential conflicts of interest and recuse themselves from the process if there are any concerns about their ability to objectively evaluate the evidence and make an unbiased decision.”

The letter sent today questions the FDA about their decision to absolve members of the panel of their potential conflicts of interest, the FDA disclosure policy, their plans to handle this situation and what, if any changes the FDA plans to make in order to avoid any further industry influence on the outcome of advisory committee decisions.

For more information on Rep. Markey’s work on drug safety issues, cox-2 inhibitors and copies of the letters sent to the FDA, please go to <http://www.house.gov/markey/healthgen.htm>

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